BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pharmacia - Pfizer EEIG submitted on 31 October 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) through the centralised procedure for Onsenal, which was designated as an orphan medicinal product (EU/3/01/070) on 20 November 2001.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Dr P. Rossi Co-Rapporteur: Dr M. Ainsworth

Orphan Drugs:

Celecoxib was designated as an orphan medicinal product in the following indication: Treatment of Familial Adenomatous Polyposis (FAP).

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

Celecoxib has been given a Marketing Authorisation in all EU countries, through the Mutual Recognition Procedure, for the indication "symptomatic relief in the treatment of osteoarthritis (OA) or rheumatoid arthritis (RA)".

Celecoxib has been given a Marketing Authorisation worldwide for the OA/RA indication (pending in Japan) and for the Familial Adenomatous Polyposis (FAP) indication in the following countries: Argentina, Australia, Brazil, Chile, Hong Kong, Korea, Mexico, Philippines, USA and Venezuela (pending in Canada, Colombia, Malaysia, New Zealand, Peru, Singapore and Uruguay).

2. Steps taken for the assessment of the product

- The procedure started on 20 November 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 4 February 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 30 January 2002.
- During the meeting on 19 – 21 March 2002 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 22 March 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 14 June 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 29 August 2002.
- During the CPMP meeting on 17 – 19 September 2002 the CPMP adopted a list of outstanding issues to be addressed by the applicant in writing and if necessary in an oral explanation. The list of outstanding issues was sent to the applicant on 20 September 2002.
- The applicant provided written information on these outstanding issues to all CPMP members on 28 November 2002.
- The Rapporteur/Co-Rapporteurs' joint review on the applicant's responses to the list of outstanding issues was circulated to all CPMP members on 7 January 2003.

- During the CPMP meeting on 21 – 23 January 2003, outstanding issues were addressed by the applicant during a hearing before the CPMP on 22 January 2003.
- During the meeting on 21 – 23 January 2003 the CPMP adopted a list of outstanding issues, to be addressed by the applicant in writing. The list of outstanding issues was sent to the applicant on 23 January 2003.
- The applicant provided written information on these outstanding issues to all CPMP members on 28 February 2003.
- The Rapporteur/Co-Rapporteurs' joint review on the responses to the list of outstanding issues was circulated to all CPMP members on 7 March 2003.
- During the meeting on 18 – 19 March 2003 the CPMP adopted a list of outstanding issues, to be addressed by the applicant in writing. The list of outstanding issues was sent to the applicant on 20 March 2003.
- The applicant provided written information on these outstanding issues to all CPMP members on 30 April 2003.
- In the margin of the CPMP meeting on 20 – 22 May 2003, an ad-hoc clinical expert meeting took place on 19 May 2003 and a report was adopted by the CPMP on 22 May 2003 (Annex 10).
- During the CPMP meeting on 24 - 26 June 2003, outstanding issues were addressed by the applicant on 24 June 2003 during an oral hearing before the CPMP.
- During the meeting on 24 – 26 June 2003 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation under exceptional circumstances to Onsenal on 26 June 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 October 2003.